

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

RIGEL PHARMACEUTICALS, INC.,
1180 Veterans Boulevard
South San Francisco, California 94080,

Plaintiff,

v.

HON. DAVID J. KAPPOS, in his official
capacity as Director of the United States Patent
and Trademark Office and Under Secretary of
Commerce for Intellectual Property
Office of General Counsel, United States
Patent and Trademark Office, P.O. Box 15667,
Arlington, Virginia 22215
Madison Building East, Room 10B20,
600 Dulany Street, Alexandria, Virginia 22314,

Defendant,

Civil Action No. _____

Jury Trial Demanded

COMPLAINT

Plaintiff Rigel Pharmaceuticals, Inc. ("Rigel"), for its complaint against the Honorable David J. Kappos, states as follows:

NATURE OF THE ACTION

1. This is an action by the assignee of United States Patent No. 7,517,886 ("the '886 patent") seeking judgment, pursuant to 35 U.S.C. § 154(b)(4)(A), that the patent term adjustment for the '886 patent be changed from 740 days to 1104 days.
2. This action arises under 35 U.S.C. § 154 and the Administrative Procedure Act, 5 U.S.C. §§ 701-706.

THE PARTIES

3. Defendant David J. Kappos is the Under Secretary of Commerce for Intellectual Property and the Director of the United States Patent and Trademark Office ("USPTO"), acting in his official capacity. The Director is the titular head of the USPTO, is responsible for superintending or performing all duties required by law with respect to the granting and issuing of patents, and is designated by statute as the official responsible for determining the period of patent term adjustments under 35 U.S.C. § 154.

4. Plaintiff Rigel is a corporation organized under the laws of Delaware, having a principal place of business at 1180 Veterans Boulevard, South San Francisco, California 94080.

JURISDICTION AND VENUE

5. This Court has jurisdiction to hear this action and is authorized to issue the relief sought pursuant to 28 U.S.C. §§ 1331, 1338(a) and 1361, 35 U.S.C. § 154(b)(4)(A) and 5 U.S.C. §§ 701-706.

6. Venue is proper in this district by virtue of 35 U.S.C. § 154(b)(4)(A).

7. This Complaint is timely filed in accordance with 35 U.S.C. § 154(b)(4)(A) and Federal Rule of Civil Procedure 6(a)(3).

BACKGROUND

8. Rajinder Singh, Ankush Argade, Donald G. Payan, Jeffrey Clough, Holger Keim, Somasekhar Bhamidipati, Catherine Sylvain, and Hui Li are the inventors for patent application number 10/631,029 ("the '029 application"), entitled "Methods of Treating or Preventing Autoimmune Diseases with 2,4-pyrimidinediamine Compounds," which issued as the '886 patent. The '886 patent concerns methods of treating or preventing autoimmune diseases. The

first page of the '886 patent is attached hereto as Exhibit A. The '886 patent is 300 pages long and the remaining pages are irrelevant to this action.

9. Plaintiff Rigel is the assignee of the '886 patent, as evidenced by records in the USPTO, and is the real party in interest in this case.

10. 35 U.S.C. § 154 requires that the Director of the USPTO grant a patent term adjustment in accordance with the provisions of section 154(b). Specifically, 35 U.S.C. § 154(b)(3)(D) states that “[t]he Director shall proceed to grant the patent after completion of the Director's determination of a patent term adjustment under the procedures established under this subsection, notwithstanding any appeal taken by the applicant of such determination.”

11. In calculating the patent term adjustment, the Director has to take into account USPTO delays under 35 U.S.C. § 154(b)(1), any overlapping periods in the USPTO delays under 35 U.S.C. § 154(b)(2)(A), and any applicant delays under 35 U.S.C. § 154(b)(2)(C).

12. Under 35 U.S.C. § 154(b)(4)(A), “[a]n applicant dissatisfied with a determination made by the Director under paragraph (3) shall have remedy by a civil action against the Director filed in the United States District Court for the District of Columbia within 180 days after the grant of the patent. Chapter 7 of title 5 shall apply to such action.”

CLAIM FOR RELIEF

13. The allegations of paragraphs 1-12 are incorporated in this claim for relief as if fully set forth herein.

14. The '029 application was filed on July 29, 2003, and issued as the '886 patent on April 14, 2009.

15. The patent term adjustment for the '886 patent, as determined by the USPTO under 35 U.S.C. § 154(b), and listed on the face of the '886 patent, is 740 days. (See Ex. A).

16. The determination of the 740-day patent term adjustment is in error.
17. Pursuant to 35 U.S.C. § 154(b)(1)(B), the USPTO failed to properly account for the period of time between the date that was three years after the actual filing date of the '029 application and the date that the '029 application issued as the '886 patent.
18. Under 35 U.S.C. § 154(b)(1)(A), plaintiff Rigel is entitled to a 735-day adjustment to the term of the '886 patent, which is the number of days attributable to USPTO examination delay ("A Delay"), as detailed by the following sub-paragraphs:
 - a. issuing a first action under 35 U.S.C. § 132 fourteen (14) months and 327 days after the '029 application was filed, 35 U.S.C. § 154(b)(1)(A)(i);
 - b. issuing an Office Action four (4) months and 102 days after the applicants' Response filed on February 22, 2006, 35 U.S.C. § 154(b)(1)(A)(ii); and
 - c. issuing the '886 patent four (4) months and 306 days after the applicants paid the issue fee, 35 U.S.C. § 154(b)(1)(A)(iv).
19. Under 35 U.S.C. § 154(b)(1)(B), plaintiff Rigel is entitled to an additional 990-day adjustment to the term of the '886 patent, which is the number of days by which the issue date of the '886 patent exceeds three years from the filing date of the application ("B Delay"). The three-year delay period of 990 days runs from July 30, 2006 (the date that was three years after the filing date of the '029 application) until April 14, 2009 (the date on which the patent issued).
20. Section 35 U.S.C. § 154(b)(2)(A) states that "to the extent . . . periods of delay attributable to grounds specified in paragraph [154(b)(1)] overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed."

21. This Court, in *Wyeth v. Dudas*, 580 F. Supp. 2d 138 (D.D.C. Sept. 30, 2008), issued an opinion explaining the proper method for calculating patent term adjustments under 35 § 154(b).

22. Under this Court's decision in *Wyeth*, "the 'A period' and 'B period' overlap only if they occur on the same calendar day or days." *Id.*, 580 F. Supp. 2d at 140.

23. Under *Wyeth*, the plaintiff is entitled to both the "A Delay" of 735 days and the "B Delay" of 990 days, minus any overlap that occurs on the same calendar days.

24. The A and B periods overlap for a total of 371 calendar days, as detailed by the following sub-paragraphs:

- a. 65 days for the period between July 30, 2006 (the beginning of the 3-year delay period) and October 2, 2006 (issuance of first office action on the merits); and
- b. 306 days for the period between June 13, 2008 and April 14, 2009 (the delay in issuance of the '886 patent after payment of the Issue Fee by the applicants).

25. The total period of USPTO delay is therefore 1,354 days, which is the sum of the period of "A Delay" (735 days) and the period of "B Delay" (990 days) minus any overlap (371 days).

26. Under 35 U.S.C. § 154(b)(2)(C), the total period of USPTO delay is reduced by the period of cumulative applicant delay. During prosecution of the '029 application, the cumulative applicant delay was 250 days. The applicants filed responses to Office Actions three (3) months plus 92, 65, and 3 days, respectively, after the mailing of the respective actions, and

filed an information disclosure statement 90 days after filing a response to an Office Action, as detailed by the following sub-paragraphs:

- a. the applicants filed a response to the Office Action mailed August 22, 2006 three (3) months and 92 days after mailing, 35 U.S.C. § 154(b)(2)(C)(ii);
- b. the applicants filed a response to the Office action mailed October 2, 2006 three (3) months and 65 days after mailing, 35 U.S.C. § 154(b)(2)(C)(ii);
- c. the applicants filed a response to the Office action mailed June 15, 2007 three (3) months and 3 days after mailing, 35 U.S.C. § 154(b)(2)(C)(ii); and
- d. the applicants filed an information disclosure statement 90 days after filing a response to an Office Action on March 8, 2007, 35 U.S.C. § 154(b)(2)(C)(iii) and 37 CFR 1.704(c)(8).

27. Accordingly, the correct patent term adjustment under 35 U.S.C. § 154 is 1,104 days, which is the difference between the total period of USPTO delay (1,354 days) and the period of applicant delay (250 days).

28. On June 11, 2009, the patentees timely filed with the USPTO a Request for Reconsideration of Patent Term Adjustment under 37 CFR 1.705 (b)-(d) ("Request for Reconsideration") for the '886 patent, requesting that the patentees be granted a corrected final patent term adjustment of 1,104 days based on this Court's explanation of how to calculate overlap under 35 U.S.C. § 154(b).

29. On September 9, 2009, in its Decision on Request for Reconsideration of Patent Term Adjustment (attached as Exhibit B), the USPTO dismissed patentees' Request for

Reconsideration of Patent Term Adjustment because “[p]atentees’ calculation of the period of overlap is inconsistent with the Office’s interpretation of this provision.”

30. The USPTO’s imposition of only 740 days of patent term adjustment for the ‘886 patent is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law and in excess of statutory jurisdiction, authority or limitation.

WHEREFORE, Plaintiff Rigel respectfully prays that this Court:

- A. Issue an Order changing the period of patent term adjustment for the ‘886 patent from 740 days to 1,104 days and requiring the USPTO to alter the term of the ‘886 patent to reflect that 1,104-day patent term adjustment; and
- B. Grant such other and further relief as the nature of the case may admit or require and as may be just and equitable.

JURY DEMAND

Plaintiff Rigel demands a jury trial on all issues so triable.

Respectfully submitted,
BLANK ROME LLP



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EXHIBIT A

(12) **United States Patent**
Singh et al.(10) **Patent No.:** US 7,517,886 B2
(45) **Date of Patent:** Apr. 14, 2009(54) **METHODS OF TREATING OR PREVENTING AUTOIMMUNE DISEASES WITH 2,4-PYRIMIDINEDIAMINE COMPOUNDS**(75) Inventors: **Rajinder Singh**, Belmont, CA (US); **Ankush Argade**, Foster City, CA (US); **Donald G. Payan**, Hillsborough, CA (US); **Jeffrey Clough**, Redwood City, CA (US); **Holger Keim**, Menlo Park, CA (US); **Somasekhar Bhamidipati**, Foster City, CA (US); **Catherine Sylvain**, Burlingame, CA (US); **Hui Li**, Millbrae, CA (US)(73) Assignee: **Rigel Pharmaceuticals, Inc.**, South San Francisco, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 740 days.

(21) Appl. No.: 10/631,029

(22) Filed: Jul. 29, 2003

(65) **Prior Publication Data**

US 2007/0060603 A1 Mar. 15, 2007

Related U.S. Application Data

(60) Provisional application No. 60/399,673, filed on Jul. 29, 2002, provisional application No. 60/443,949, filed on Jan. 31, 2003, provisional application No. 60/452,339, filed on Mar. 6, 2003.

(51) **Int. Cl.****A61K 31/4965** (2006.01)(52) **U.S. Cl.** 514/256; 514/825; 514/903(58) **Field of Classification Search** 514/256, 514/825, 903
See application file for complete search history.(56) **References Cited****U.S. PATENT DOCUMENTS**

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Primary Examiner—Raymond J. Henley, III

(74) Attorney, Agent, or Firm—Foley & Lardner LLP; James J. Diehl

(57) **ABSTRACT**

The present invention provides methods of treating or preventing autoimmune diseases with 2,4-pyrimidinediamine compounds, as well as methods of treating, preventing or ameliorating symptoms associated with such diseases. Specific examples of autoimmune diseases that can be treated or prevented with the compounds include rheumatoid arthritis and/or its associated symptoms, systemic lupus erythematosus and/or its associated symptoms and multiple sclerosis and/or its associated symptoms.

EXHIBIT B



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
 United States Patent and Trademark Office
 P.O. Box 1450
 Alexandria, VA 22313-1450
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SEP 09 2009

OFFICE OF PETITIONS

In re Patent No. 7,517,886 :
 Singh et al. : DECISION ON
 Issue Date: April 14, 2009 : REQUEST FOR RECONSIDERATION
 Application No. 10/631,029 : OF
 Filed: July 29, 2003 : PATENT TERM ADJUSTMENT
 Attorney Docket No. 09-563-US :
 :

This is in response to the "PETITION FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT FILED UNDER 37 CFR 1.705(d)," filed June 11, 2009, requesting that the patent term adjustment determination for the above-identified patent be changed from seven hundred forty (740) days to one thousand one hundred and four (1,104) days.

The request for reconsideration of patent term adjustment is **DISMISSED**.

On April 14, 2009, the above-identified application matured into U.S. Patent No. 7,517,886 with a patent term adjustment of 740 days. This request for reconsideration of patent term adjustment (including the required fee) was timely filed within two months of the issue date of the patent. See 1.705(d).

Patentees request recalculation of the patent term adjustment based on the decision in *Wyeth v. Dudas*, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008). Patentees assert that pursuant to *Wyeth*, a PTO delay under §154(b)(1)(A) overlaps with a delay under §154(b)(1)(B) only if the delays "occur on the same day." Patentees maintain that a portion of the period of adjustment due to the Three Year Delay by the Office, pursuant to 37 CFR § 1.703(b), 619 of the 990 days, and the period of adjustment due to examination delay, pursuant to 37 CFR §1.702(a), of 735 days do not overlap as these periods do not occur on the same day.

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Patentees argue that the period of adjustment due to the Three Year Delay by the Office, pursuant to 37 CFR § 1.703(b), is 990 days. This 990 day period is calculated based on the application having been filed under 35 U.S.C. §111 on July 29, 2003, and the patent having not issued until April 14, 2009, three years and 990 days later. Patentees assert that in addition to this 990 day period, they are entitled to a period of adjustment due to examination delay, pursuant to 37 CFR §1.702(a), totalling 735 days. This 735 day period is the sum of:

- a period of delay of 327 days for the failure by the Office to mail at least one of a notification under 35 U.S.C. 132 not later than fourteen months after the date on which the application was filed under 35 U.S.C. 111(a), pursuant to § 1.702(a)(1);
- a period of delay of 102 days for the failure by the Office to respond to a reply under 35 U.S.C. 132 not later than four months after the date on which the reply was filed, pursuant to § 1.702(a)(2); and
- a period of delay of 306 days for the failure by the Office to issue a patent not later than four months after the date on which the issue fee was paid and all outstanding requirements were satisfied, pursuant to § 1.702(a)(4).

Under 37 CFR § 1.703(f), applicants are entitled to a period of patent term adjustment equal to the period of delays based on the grounds set forth in 37 CFR §1.702 reduced by the period of time equal to the period of time during which applicants failed to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR §1.704. In other words, the period of Office delay reduced by the period of applicant delay. The period of reduction of 250 days for applicant delay is not in dispute. Patentees assert that the total period of Office delay is the sum of the period of Three Years Delay (990 days) and the period of Examination Delay (735 days) to the extent that these periods of delay are not overlapping.

Further, patentees articulate the periods of overlap as follows:

Patentees contend that 65 days of the period of delay of 102 days for the Office's failure to respond to a reply under 35 U.S.C. 132 not later than four months after the

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date on which the reply was filed, pursuant to § 1.702(a)(2) (June 23, 2006 to October 2, 2006) overlaps with the Three Year Delay period (July 30, 2006 to April 14, 2009). Patentees assert that this overlapping period is the 65 days running from July 30, 2006 to October 2, 2006.

In addition, patentees contend that the full 306 days for the failure by the Office to issue a patent not later than four months after the date on which the issue fee was paid and all outstanding requirements were satisfied, pursuant to § 1.702(a)(4), (June 13, 2008 to April 14, 2009) overlaps with a portion of the Three Year delay period (July 30, 2006 to April 14, 2009). Patentees assert that this overlapping period is the entire 306 days from June 13, 2008 to April 14, 2009.

Thus, according to patentees the total period of overlap is 371 days.

Accordingly, patentees submit that the total period of Office Delay is 1,354 days, which is the sum of the period of Three Year Delay (990 days) and the period of Examination Delay (735 days), reduced by the period of overlap (371 days).

As such, patentees assert entitlement to a patent term adjustment of 1,104 days (990 +735 reduced by 371 overlap -250 for applicant delay).

The Office agrees that the patent issued 3 years and 990 days after its filing date. The Office agrees that the actions detailed above were not taken within the specified time frames, and thus, the Office entered a period of adjustment of 735 days. At issue is whether patentees should accrue 619 (adjusted for overlap, per patentees' definition of overlap) days of patent term adjustment for the Office taking in excess of three years to issue the patent, as well as, 735 days for Office failure to take certain actions within a specified time frames (or examination delay).

The Office contends that 735 days overlap. Patentees' interpretation of the period of overlap has been considered and found to be incorrect. Patentees' calculation of the period of overlap is inconsistent with the Office's interpretation of this

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provision. 35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

to the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

Likewise, 37 CFR 1.703(f) provides that:

To the extent that periods of delay attributable to the grounds specified in §1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.

As explained in *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B). Accordingly, the Office implements the overlap provision as follows:

If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). Thus, any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See 35 U.S.C. 154(b)(1)(B), 35 U.S.C. 154(b)(2)(A), and 37 CFR § 1.703(f). See *Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule*, 65 Fed. Reg. 56366 (Sept. 18, 2000). See also *Revision of Patent Term Extension and Patent Term Adjustment Provisions; Final*

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Rule, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (May 18, 2004). See also *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, 69 Fed. Reg. 34283 (June 21, 2004).

The current wording of § 1.703(f) was revised in response to the misinterpretation of this provision by a number of applicants. The rule was slightly revised to more closely track the corresponding language of 35 U.S.C. 154(b)(2)(A). The relevant portion differs only to the extent that the statute refers back to provisions of the statute whereas the rule refers back to sections of the rule. This was not a substantive change to the rule nor did it reflect a change of the Office's interpretation of 35 U.S.C. 154(b)(2)(A). As stated in the *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

This interpretation is consistent with the statute. Taken together the statute and rule provide that to the extent that periods of delay attributable to grounds specified in 35 U.S.C. 154(b)(1) and in corresponding § 1.702 overlap, the period of adjustment granted shall not exceed the actual number of days the issuance of the patent was delayed. The grounds specified in these sections cover the A) guarantee of prompt Patent and Trademark Office responses, B) guarantee of no more than 3 year application pendency, and C) guarantee or adjustments for delays due to interference, secrecy orders and appeals. A section by section analysis of 35 U.S.C. 154(b)(2)(A) specifically provides that:

Section 4402 imposes limitations on restoration of term. In general, pursuant to [35 U.S.C.] 154(b)(2)(A)-(C), total adjustments granted for restorations under [35 U.S.C. 154](b)(1) are reduced as follows: (1) To the extent that there are multiple grounds for extending the term of a

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patent that may exist simultaneously (e.g., delay due to a secrecy order under [35 U.S.C.] 181 and administrative delay under [35 U.S.C.] 154(b)(1)(A)), the term should not be extended for each ground of delay but only for the actual number of days that the issuance of a patent was delayed; See 145 Cong. Rec. S14,718¹

As such, the period for over 3 year pendency does not overlap only to the extent that the actual dates in the period beginning three years after the date on which the application was filed overlap with the actual dates in the periods for failure of the Office to take action within specified time frames. In other words, consideration of the overlap does not begin three years after the filing date of the application.

In this instance, the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A) is the entire period during which the application was pending before the Office, July 29, 2003 to April 14, 2009. (There were no periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)). 735 days of patent term adjustment were accorded prior to the issuance of the patent for the Office failing to respond within specified time frames during the pendency of the application. All of these 735 days overlap with the 990 days for Office delay in issuing the patent. The Office took 14 months and 327 days to issue a first Office action, four months and 102 days to mail a non-final Office action in response to response filed May 7, 2008, and the Office took 4 months and 306 days to issue the patent after the issue fee and all outstanding requirements were satisfied. Otherwise, the Office took all actions set forth in 37 C.F.R. § 1.702(a) within the prescribed timeframes. Nonetheless, given the initial 735 days of Office delay and the time allowed within the timeframes for processing and examination, the patent issued, three years and 990 days after its filing date. The Office properly entered 255 days of patent term adjustment since the period of delay of 990 days attributable to the delay in the issuance of the patent overlaps with the adjustment of 735 days attributable to grounds specified in §§ 1.702(a)(1), (2), and (4).

¹ The AIPA is title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999 (S. 1948), which was incorporated and enacted as law as part of Pub. L. 106-113. The Conference Report for H.R. 3194, 106th Cong. 1st Sess. (1999), which resulted in Pub. L. 106-113, does not contain any discussion (other than the incorporated language) of S. 1948. A section-by-section analysis of S. 1948, however, was printed in the Congressional Record at the request of Senator Lott, See 145 Cong. Rec. S14,708-26 (1999) (daily ed. Nov. 17, 1999).

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Accordingly, at issuance, the Office properly entered 255 additional days of patent term adjustment for the Office taking in excess of 3 years to issue the patent for a total Office delay of 990 days.

In view thereof, the Office affirms that the correct revised determination of patent term adjustment at the time of the issuance of the patent is 740 days.

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e). No additional fees are required.

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